

### REMARKS

This communication is in response to final office action mailed on August 11, 2011 rejecting claims 1, 4-5, 9-10, 13-14, 16, and 21-23

#### **Objection to the Amendment of Claim 23 and Rejection of Claim 23 under 35 U.S.C. § 112**

The office action mailed on August 11, 2011 objected to claim 23, newly presented on June 1, 2011, as introducing new matter. We disagree.

The specification describes an ostomy bag that employs an adhesive wafer that permits the user or the care provider to remove a portion of the ostomy bag away from the wafer to evaluate the health of the stoma. With specific reference to Figure 1, the specification at page 9, lines 10-22 describes that a stiffening element (9) is provided as a flat ring and that "the shape of such ring should correspond to shape of the attachment zone and may e.g. be circular or elliptical." Figure 1 illustrates the attachment zone 8 and the stiffening element 9 were a first part of the attachment zone at 8 is removable from the rear 3 of the ostomy bag and a second part 7' of the wafer is permanently attached to the rear 3 of the ostomy bag. The specification teaches at page 16, lines 8-14 that in the embodiment illustrated in figures 4 and 5 stiffening element 31 is in the form of a circular ring 32. Consequently, the stiffening elements 9, 31 described in the specification include circular rings, where the shape of the circular ring should correspond to the shape of the attachment zone 8. With reference to Figure 1, the circular stiffening element 9 is shown to be concentric with the attachment zone 8.

Claim 23 recites "wherein the first portion and the second portion of the adhesive wafer are each located at an equal radial distance from the hole in the adhesive wafer." Figure 1 illustrates that the circular stiffening element 9 is concentric with the attachment zone 8. Consequently, the first portion 7' that is permanently secured at 3 to the rear of the bag must be located at an equal radial distance from a hole 6 from the second portion 8 that is on attached to the rear wall 3 of the bag.

Thus, the specification as filed teaches at the first portion 7' and the second portion 8 are each located at an equal radial distance from the hole 6 of the adhesive wafer, as recited in claim 23.

The drawings may provide the basis for subsequent amendments to the Specification without producing prohibitory new matter. *In re Wolfensperger*, 302 F.2d 950, 133 USPQ 537 (C.C.P.A. 1962); M.P.E.P. §2163.02. Under *Wolfensperger*: “The practical, legitimate inquiry in each case of this kind is what the drawing in fact discloses to one of skill in the art. Whatever it does disclose may be added to the Specification in words without violation of the statute and rule which prohibit ‘new matter,’ 35 U.S.C. §132, rule 118, for the simple reason that what is originally disclosed cannot be ‘new matter’ within the meaning of this law.” (emphasis added) 133 USPQ at 542. In light of this understanding, it is respectfully submitted that claim 23 is supported in the Specification at least through an implicit or inherent disclosure of Figure 1. M.P.E.P. §2163 I.B.

No new matter has been added. It is respectfully requested that the objection to claim 23 and the rejection under 35 U.S.C. §112 be withdrawn.

**Claim rejections under 35 U.S.C. § § 102 and 103**

**Claims 1 and 21 were rejected under 35 U.S.C. § 102(b) as anticipated by EP 1 181 910 (“EP ‘910”).**

EP ‘910 discloses at field 57 (on the front page of the document) an adhesive flange 2. The adhesive flange 2 attaches to the wearer at 21. Opposite the side of the wearer, the adhesive flange 2 has a permanently attached inner ring 20 and an outer ring 21 having a temporary, manually-separable bond 25. The ring 20 is permanently attached to the bag at 23 (column 3, lines 10-13). Portion 24 is a non-adhesive sheet. Thus, no portion of EP ‘910 can be resealed to the ostomy bag.

In contrast, the present application teaches an adhesive wafer that has a first portion that is permanently attached to the ostomy bag and a separate second portion that allows the ostomy bag to be peeled away from the adhesive wafer to view the condition and the health of the stoma (see page 6, lines 7-20 and Figure 1 illustrating the bag removed from the attachment zone).

In particular, independent claim 1 requires an adhesive wafer having a first portion that is permanently secured to the rear wall of the bag and a second portion that is adhesively attachable to the rear wall of the bag and removable from and resealable to the rear wall of the bag to allow a portion of the adhesive wafer to be removed from the bag for viewing the stoma.

Support for the language of amended independent claim 1 is located in the application as filed at least at page 6, page 9, lines 5-8, page 15, lines 1-15, and as illustrated in Figure 1 where the bag has been removably separated from the attachment zone for observation of a stoma positioned within the hole 6.

EP '910 fails to teach or suggest an adhesive wafer having a first portion that is permanently secured to the rear wall of the bag and a second portion that is adhesively attachable to the rear wall of the bag and removable from and resealable to the rear wall of the bag to allow a portion of the adhesive wafer to be removed from the bag for viewing the stoma. The perimeter of the inner ring 20 of EP '910 is "permanently" attached to the bag at 23. Sheet 24 is non-adhesive (column 3, lines 13-15). No part of the inner ring 20 or the outer ring 21 is resalable to the bag.

In addition, EP '910 fails to teach or suggest a second portion that is removable from the rear wall of the bag to allow a portion of the adhesive wafer to be removed from the bag for viewing the stoma.

Thus, claim 1 is novel and not rendered obvious by EP '910.

Claim 21 further defines patentably distinct amended independent claim 1.

Thus, it is respectfully requested that the rejection to claims 1 and 21 under 35 U.S.C. § 102(b) be withdrawn.

**Claims 13-14 were rejected under 35 U.S.C. §102 (b) as anticipated by Whiteside, US2001/0020156 ("Whiteside").**

Whiteside provides a flange 2 including two discs 21, 22. Layer 26 is an adhesive and layer 25 is a non-adhesive sheet.

Independent claim 13 has been amended to require a bag having a rear wall having an opening for receiving a stoma and surrounded by an edge having a first edge part permanently secured to a first part of an attachment zone and a second remaining edge part attachable to the attachment zone; and an adhesive layer disposed between the second remaining edge part and the attachment zone, where the adhesive layer allows the second remaining edge part to be removable from the attachment zone to allow a portion of the adhesive wafer to be removed from the bag for viewing the stoma.

Support for the language of amended independent claim 1 is located in the application as filed at least at page 6, page 9, lines 5-8, page 15, lines 1-15, and as illustrated in Figure 1 where the bag has been removably separated from the attachment zone for observation of a stoma positioned within the hole 6.

Even if disc 22 is removed from disc 21 in Whiteside, no portion of the stoma will be visible. Whiteside thus fails to teach or suggest a second remaining edge part attachable to the attachment zone that is removable from the attachment zone to allow a portion of the adhesive wafer to be removed from the bag for viewing the stoma, as required by amended independent claim 13.

Claim 14 further defines patentably distinct amended independent claim 13.

Thus, it is respectfully requested that the rejections to claims 13-14 under 35 U.S.C. § 102(b) be withdrawn.

**Claims 4-5 and 9-10 were rejected under 35 U.S.C. § 103(a) as unpatentable over EP ‘910 in view of Thomas, U.S. Pat. No. 4,865,594 (“Thomas”).**

Thomas is cited as disclosing a stiffening layer.

EP ‘910 fails to teach or suggest all limitations of amended independent claim 1. Thomas fails to cure the deficiencies of EP ‘910 in establishing the requisite *prima facie* case of obviousness, such that EP ‘910, alone or in combination with Thomas, fails to render claim 1 or its dependent claims as obvious.

Thus, it is respectfully requested that the rejections to claims 4-5 and 9-10 under 35 U.S.C. § 103(a) be withdrawn.

**Claims 16 was rejected under 35 U.S.C. § 103(a) as unpatentable over Whiteside in view of Thomas and claim 22 was rejected under 35 U.S.C. § 103(a) as unpatentable over EP ‘910 in view of Whiteside.**

Both Whiteside and EP ‘910 fail to teach or suggest all limitations of amended independent claims 1 and 13. Thomas, alone or in combination with either of these references, fails to cure the deficiencies of the cited primary references in establishing the requisite *prima facie* case of obviousness.

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Thus, it is respectfully requested that the rejections to claims 16 and 22 under 35 U.S.C. § 103(a) be withdrawn.

### **CONCLUSION**

It is believed that pending claims 1, 4-5, 9-10, 13-14, 16, and 21-23 recite patentable subject matter and are in condition for allowance.

The Examiner is invited to telephone the undersigned if issues remain outstanding.

The office is authorized to charge any fees actually due and credit any overpayment to deposit account 50-4439.

Respectfully submitted,

Date: October 7, 2011

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